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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	- X
SECURITIES AND EXCHANGE COMMISSION,	:
Plaintiff,	: 08 Civ. 02979 (LAK) : ECF CASE
- against -	:
- -	: DECLARATION OF : NAZAR ALTUN
BIOVAIL CORPORATION, EUGENE N. MELNYK, BRIAN CROMBIE, JOHN MISZUK and KENNETH G. HOWLING,	:
Defendants.	; ; ;
	: -X

NAZAR ALTUN declares pursuant to 28 U.S.C § 1746 that:

- 1. I am associated with the law firm of Fried, Frank, Harris, Shriver & Jacobson LLP, attorneys for defendant Kenneth G. Howling ("Mr. Howling").
- 2. I submit this declaration in support of Mr. Howling's Motion to Dismiss the Second Claim in the Amended Complaint.
- 3. Attached as Exhibit A is a true and correct copy of the Amended Complaint filed by the Securities and Exchange Commission in the above captioned matter, dated July 31, 2008.

- Attached as Exhibit B is a true and correct copy of the press release issued by 4. Biovail Corporation ("Biovail") on October 3, 2003 (the "October 3rd Press Release").
- Attached as Exhibit C is a true and correct copy of a draft of the October 3rd Press 5. Release, written by Brian Crombie on October 2, 2003.
- 6. Attached as Exhibit D is a true and correct copy of a draft of the press release issued by Biovail on October 8, 2003.

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 22, 2008.

Nazar.Altun@friedfrank.com

EXHIBIT A

ANDREW M. CALAMARI ASSOCIATE REGIONAL DIRECTOR **Attorneys for Plaintiff** SECURITIES AND EXCHANGE COMMISSION **New York Regional Office** 3 World Financial Center New York, NY 10281 (212) 336-1120

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff.

-against-

BIOVAIL CORPORATION, EUGENE N. MELNYK, BRIAN CROMBIE, JOHN MISZUK, and KENNETH G. HOWLING,

Defendants.



08 Civ. 02979 (LAK) **ECF CASE**

AMENDED COMPLAINT

Plaintiff Securities and Exchange Commission, for its Amended Complaint against Defendants Biovail Corporation ("Biovail" or the "Company"), Eugene N. Melnyk, Brian Crombie, John Miszuk, and Kenneth G. Howling (collectively, "Defendants"), alleges as follows:

SUMMARY OF ALLEGATIONS

- 1. This case involves chronic fraudulent conduct including financial reporting fraud and other intentional public misrepresentations by Biovail Corporation, a Canadian pharmaceutical company whose common stock is traded on the New York and Toronto stock exchanges. Obsessed with meeting quarterly and annual earnings guidance, Biovail's executives repeatedly overstated earnings and hid losses in order to deceive investors and create the appearance of achieving that goal. And, when it ultimately became impossible to continue to conceal the Company's poor performance, Biovail actively misled investors and analysts as to its cause. This corrupt strategy was employed by Biovail's most senior officers: Eugene Melnyk, former chairman and chief executive officer; Brian Crombie, former chief financial officer; John Miszuk, former vice president, controller, and assistant secretary; and Kenneth G. Howling, former chief financial officer and vice president of finance and corporate affairs.
- 2. The financial reporting fraud involves three accounting schemes that affected reporting periods from 2001 to 2003. They are: (1) a transaction through which Biovail, over several reporting periods in 2001 and 2002, improperly moved off its financial statements and onto the financial statements of a special purpose entity known as Pharmatech the expenses incurred in the research and development of some of Biovail's products that totaled approximately \$47 million through September 30, 2002 and related liabilities that exceeded approximately \$51 million through that date; (2) a fictitious bill and hold transaction that Biovail concocted to record approximately \$8 million in revenue in the second quarter of 2003; and (3) the intentional misstatement of foreign exchange losses that caused Biovail's second quarter 2003 loss to be understated by about \$3.9 million.

- In addition, in October 2003, Biovail intentionally and falsely attributed nearly 3. half of its failure to meet its third quarter 2003 earnings guidance to a truck accident involving a shipment of Biovail's product, Wellbutrin XL. Biovail intentionally misstated both the effect of the accident on Biovail's third quarter earnings as well as the value of the product involved in the truck accident. The accident, in fact, had no effect on third quarter earnings.
- Each of Biovail's fraudulent accounting schemes had a material effect on 4. Biovail's financial statements for the relevant quarters and years and was engineered by Biovail's senior management in order to manage Biovail's earnings. In effecting these schemes, Biovail management also intentionally deceived its auditors as to the true nature of the transactions. The truck accident misstatements were intended to and did mislead analysts and the investing public concerning the significance of Biovail's failure to meet its own earnings guidance.
- 5. Biovail's then-chairman and chief executive, Eugene Melnyk, also violated share ownership disclosure provisions by failing to identify in his Schedule 13D filings his beneficial ownership of Biovail shares held by several trusts he settled in the late 1990s. Melnyk transferred the Biovail shares from his personal holdings to the trusts. However, because Melnyk continued to exercise both investment and trading authority over the shares in the trusts, Melnyk remained a beneficial owner of the securities and was under a legal obligation to disclose that ownership and material changes to it.

VIOLATIONS

- 6. By virtue of the foregoing conduct:
 - Biovail, directly or indirectly, singly or in concert, has engaged in acts, a. practices, and courses of business that constitute violations of Section 17(a) of the Securities Act of 1933 (the "Securities Act") [15 U.S.C. § 77q(a)], Sections 10(b) 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Securities Exchange Act of 1934 (the "Exchange Act") [15 U.S.C. §§ 78i(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1, and 13a-16, and Rule 302(b) of Regulation S-T [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1, 240.13a-16, and 232.302(b)].
 - b. Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have engaged in acts, practices, and courses of business that constitute violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].
 - Crombie, directly or indirectly, singly or in concert, has engaged in acts, c. practices, and courses of business that constitute violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

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- d. Melnyk, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].
- Crombie and Miszuk, directly or indirectly, singly or in concert, have e. engaged in acts, practices, and courses of business that constitute violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2].
- f. Crombie, directly or indirectly, singly or in concert, has engaged in acts, practices, and courses of business that constitute violations of Rule 13a-14 [17 C.F.R. § 240.13a-14].
- By virtue of the conduct described herein, Crombie and Miszuk are also g. each liable, pursuant to Section 20(e) of the Exchange Act, as an aider and abettor of Biovail's violations of Sections 10(b), 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78j(b), 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 10b-5, 12b-20, 13a-1 and 13a-16 [17 C.F.R. §§ 240.10b-5, 240.12b-20, 240.13a-1 and 240.13a-16].

JURISDICTION AND VENUE

7. The Commission brings this action pursuant to the authority conferred upon it by Section 20(b) of the Securities Act [15 U.S.C. § 77t(b)] and Section 21(d)(1) of the Exchange Act [15 U.S.C. § 78u(d)(1)] seeking to restrain and permanently enjoin Biovail, Melnyk,

Crombie, Miszuk, and Howling from engaging in the acts, practices, and courses of business alleged herein. The Commission also seeks a final judgment:

- ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any a. ill-gotten gains and to pay prejudgment interest thereon;
- ordering Biovail and Crombie to pay civil money penalties pursuant to b. Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)];
- ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to pay civil c. money penalties pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. \S 78u(d)(3)]; and
- d. permanently barring Melnyk, Crombie, Miszuk, and Howling from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 781] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 78o(d)].
- 8. This Court has jurisdiction over this action pursuant to Section 22(a) of the Securities Act [15 U.S.C. § 77v(a)] and Sections 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(e) and 78aa].
- Venue is proper under Section 22(a) of the Securities Act [15 U.S.C. § 77v] because a registered offering of Biovail's securities took place in, among other places, the Southern District of New York. Venue is proper under Section 27 of the Exchange Act [15 U.S.C. § 78aa] because certain of the transactions, acts, practices, and courses of business alleged in this Complaint took place in the Southern District of New York.

- 10. Biovail and Crombie, directly or indirectly, singly or in concert, have made use of means or instruments of transportation or communication in interstate commerce, or of the mails, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.
- 11. Biovail, Melnyk, Crombie, Miszuk, and Howling, directly or indirectly, singly or in concert, have made use of the means and instrumentalities of interstate commerce, or of the mails, or of a facility of a national securities exchange, in connection with the transactions, acts, practices, and courses of business alleged in this Complaint.

THE DEFENDANTS

- 12. <u>Biovail Corporation</u>, a foreign private issuer, is a pharmaceutical company incorporated under the laws of Ontario, Canada. Its headquarters are in Mississauga, Ontario, and it has facilities in the United States, Canada, Ireland, and Puerto Rico. As a foreign private issuer, Biovail files annual reports on Form 20-F and furnishes interim financial statements to the Commission on Form 6-K. During the relevant time period, Biovail included in its annual and interim reports financial statements purportedly prepared in accordance with both U.S. and Canadian generally accepted accounting principles. Since 2006, Biovail has been providing financial statements prepared only in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").
- 13. **Eugene Melnyk**, age 49, is a Canadian citizen and a resident of St. Philip,
 Barbados. Melnyk is the founder of Biovail and served as its chairman and as a director from
 March 1994 through June 2007. From December 2001 to October 2004, Melnyk also was

Biovail's chief executive officer. Melnyk resigned as a director and chairman of Biovail effective June 30, 2007.

- 14. <u>Brian Crombie</u>, age 49, is a Canadian citizen and a resident of Mississauga,
 Ontario. He was Biovail's chief financial officer from May 2000 to August 2004. In August
 2004, Crombie was removed as chief financial officer and became Biovail's senior vice president
 for strategic development. As of May 2007, Crombie no longer holds any position with the
 Company. Crombie's compensation during the relevant time period had salary and bonus
 components. His bonus was dependent on several factors, including whether the Company met
 certain financial targets.
- Ontario. In 2003, he was a vice president, controller, and assistant secretary of Biovail. In March 2008, he was reassigned to a non-officer position within the Company. While Miszuk is not a chartered accountant, he was the principal accounting officer for Biovail. The controllers of all of the operating groups reported to him. Corporate legal accounting as well as the consolidated reporting group also reported to him. Miszuk also was responsible for communicating with Biovail's independent auditors. Miszuk's compensation during the relevant time period had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets.
- 16. <u>Kenneth G. Howling</u>, age 51, is a U.S. citizen and a resident of Toronto, Ontario. On December 6, 2006, the Company announced Howling's promotion to his current position of senior vice-president and chief financial officer. He also was the Company's chief financial officer from 1997 to 2000. From 2000 to 2003, he was Biovail's vice president of finance, and

in 2003 he assumed additional responsibilities for external communications to investors and analysts when his title changed to vice president, finance and corporate affairs. He is a certified public accountant licensed in New Jersey, but is not a Canadian chartered accountant. In March 2008, he was reassigned to a non-officer position within the Company. Howling's compensation during the relevant time period had salary and bonus components. His bonus was dependent on several factors, including whether the Company met certain financial targets.

FACTS

A. Misrepresentations Concerning the October 2003 Truck Accident

- 17. On September 30, 2003, a truck carrying a shipment of a Biovail product, Wellbutrin XL, left Biovail's Steinbach, Manitoba, plant bound for the North Carolina facility of a major international pharmaceutical company that distributed the product (the "Distributor"). On October 1, 2003, while en route to North Carolina, the truck was involved in a multi-vehicle traffic accident on a highway in Illinois.
- 18. The value of the product on the truck that was involved in the accident was about \$5 million.
- 19. Biovail, Melnyk, Crombie, and Howling issued two press releases and made numerous other public statements declaring that the loss of revenue and income associated with the truck accident contributed significantly to Biovail's substantial revenue shortfall for the third quarter of 2003 in the amount of \$10 million to \$20 million, or about 23% to 38% of the total announced revenue shortfall for the quarter.
- 20. The press releases and other repeated public statements were materially false and misleading. The truck accident had no impact on Biovail's financial results for the quarter, as

Biovail, Melnyk, Crombie, and Howling knew or recklessly disregarded. In addition, in the press releases and other public statements, Biovail, Melnyk, Crombie, and Howling grossly overstated the revenue value of the shipment involved in the truck accident.

The Truck Accident Had No Impact on Biovail's Third Quarter Revenues

- 21. Under U.S. GAAP, revenue may be recognized on the sale of a product like Wellbutrin XL when, among other things, delivery of the product by the seller to the buyer has occurred.
- 22. Pursuant to Biovail's agreement with the Distributor, all deliveries of Wellbutrin XL were subject to the term "F.O.B., [the Distributor's] facilities in the U.S.A. (freight collect)." This "F.O.B. Destination" delivery term meant that delivery occurred and Biovail's revenue recognition would have been appropriate only when the product reached the Distributor's facilities in the United States.
- 23. Under the F.O.B. Destination shipping term the term actually in effect the truck accident had no impact on Biovail's third quarter financial results because the truck left Manitoba on September 30, which was too late for it to reach the Distributor's North Carolina facility prior to the end of the quarter. Under those circumstances, Biovail could not have recognized revenue resulting from the shipment regardless of the accident.
- 24. The deliberate misrepresentations by Melnyk, Crombie, Howling, and Biovail were based on the false premise that the delivery term was "F.O.B. Biovail," pursuant to which delivery would have occurred and Biovail could have recognized the revenue from the sale at the time the product left Biovail's facility.

- 25. However, even if the shipping term were F.O.B. Biovail, the truck accident would have had no impact on Biovail's third quarter financial results because the title to the product – and the risk associated with the accident —would have passed to the Distributor as soon as the truck left Biovail's Manitoba plant. Under those circumstances, Biovail could have recognized revenue resulting from the shipment regardless of the accident.
- 26. Nevertheless, Melnyk, Crombie, Howling, and Biovail repeatedly and falsely attributed the Company's third quarter revenue shortfall to the truck accident.

The October 3 Press Release and Conference Call

- 27. On October 3, 2003, Biovail issued a press release announcing that its third quarter 2003 "revenues [would] be below previously issued guidance and will be in the range of \$215 million to \$235 million and earnings per share of \$0.35 to \$0.45." The revenues were below the guidance the Company had issued in February 2003 by about \$45 million to \$65 million and the earnings per share range were below the February estimate by \$0.23 at both ends of the range. This was the first time that Biovail had ever failed to meet its quarterly guidance.
- 28. The October 3 press release falsely attributed a significant part of the revenue shortfall to the truck accident: "Contributing significantly to this unfavorable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a result of a traffic accident." This statement was materially false and misleading, as Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded.
- 29. The October 3 press release also grossly overstated the revenue value of the Wellbutrin XL shipment involved in the accident: "Revenue associated with this shipment is in

the range of \$10 to \$20 million." This statement was materially false and misleading, as Melnyk, Crombie, and Biovail knew or recklessly disregarded.

- 30. Howling wrote the October 3 press release. Howling's name also appears on the press release as the contact person.
- 31. Howling drafted the release based, in part, on information he received from others, including information he and Crombie received from Biovail's warehouse supervisor who was communicating with the transportation company. The information provided by the warehouse supervisor made clear that the shipment had left Biovail's warehouse on September 30, 2003 (and therefore could not have reached the Distributor's North Carolina facility by the end of the quarter) and that only one truck carrying Wellbutrin XL was involved in the accident.
- 32. In order to write the press release, Howling asked Crombie to quantify the value of the product on the truck. Although Crombie knew that the true value of the product on the truck involved in the accident was approximately \$5 million, he provided Howling with a falsely inflated valuation of \$10 to \$20 million for Howling to include in the press release.
- 33. Melnyk, Crombie, and Biovail knew or recklessly disregarded that the statement in the October 3 press release concerning the value of the product involved in the truck accident was materially false and misleading.
- 34. Howling also reviewed and used an initial draft press release that Crombie had prepared earlier in the day on October 2 and forwarded to both Melnyk and Howling. Crombie's draft stated correctly: "[s]ince the supply agreement between Biovail and its licensee stipulates FOB the licensee's warehouse, the revenue on this product cannot be recognized in Q3, 2003.

The product, either the existing shipment once approved, or replacement shipment will be shipped within ten days. However, this replacement shipment and its associated revenue will now be recognized in Q4 not Q3."

- 35. When Crombie wrote his draft press release, he had already reviewed the language of the Wellbutrin XL agreement. He knew that the F.O.B. Destination term was in effect and, therefore, the truck accident had no impact on the Company's third quarter revenue. Likewise, upon reading Crombie's draft press release on October 2, Howling knew or recklessly disregarded what it said *i.e.*, that the correct delivery term in effect for sales of Wellbutrin XL was F.O.B. Destination and that the accident had no impact on the revenue for the third quarter.
- 36. Despite the correct statements in Crombie's draft, the October 3 press release written by Howling, reviewed and edited by Melnyk and Crombie, and ultimately issued by Howling's office, under his supervision, for the Company was false and misleading because, among other things, it falsely stated that the truck accident contributed significantly to the third quarter revenue shortfall.
- 37. Also on October 3, Melnyk, Crombie, and Howling participated in a conference call with analysts in which Melnyk falsely stated: "This accident will have a negative financial impact on Biovail's third quarter revenues." Melnyk later in the call said again, "It is a third quarter item." Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded that these statements by Melnyk were materially false and misleading.
- 38. On the same conference call, Crombie falsely said, "The unfortunate incident . . . will have a material negative effect on Biovail's third quarter revenue and earnings." He also falsely told the analysts on the call, "Our contract with [the Distributor] has title change in

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Manitoba when it leaves our shipping dock." In fact, as Melnyk, Crombie, and Howling knew or recklessly disregarded, title to the product would change only upon arrival at the Distributor's facility in the United States, and therefore Biovail could not have recognized third quarter revenue on the shipment even if the accident had not occurred.

- 39. On the same call, Crombie referred to the value of the shipment as "\$15 million to \$20 million" – three to four times the actual revenue value. He also noted, "As a result of this accident, Biovail currently estimates that its total third quarter revenues from Wellbutrin XL will now be below \$10 million." Melnyk, Crombie, and Biovail knew or recklessly disregarded that these statements were materially false and misleading.
- 40. Howling participated in the October 3 conference call and helped prepare the script for it. Although he knew or recklessly disregarded that the truck accident had no impact on Biovail's third quarter financial results, he remained silent during the call and did not correct any of the materially false and misleading statements that Melnyk and Crombie made during the call claiming that the accident did have such an impact.
- 41. Following the October 3 press release and conference call, Howling was inundated with numerous inquiries from investors, analysts, and the financial press seeking details regarding the effect of the accident on Biovail's third quarter revenues. These queries included whether Biovail would have been able to record the revenue associated with this shipment in the third quarter even if the accident had not taken place. In response to these inquiries, Howling continued to state falsely that the Wellbutrin XL agreement would have allowed Biovail to recognize revenue in the ordinary course as of the date of shipment from

Biovail's warehouse but that the Company was unable to record the revenue in the third quarter in this case because of the accident.

42. On October 3, Howling also received information detailing the cost of goods that were lost in the accident. In order to respond to the inquiries from investors, analysts, and the financial press, Howling independently calculated the actual revenue associated with the Wellbutrin XL lost in the accident. His calculations demonstrated that, in order for even the low end of the valuation published by the Company – \$10 million – to have been accurate, the product would have had to carry an 80% revenue margin. Howling knew or recklessly disregarded that the actual margin for Wellbutrin XL was substantially less than 80%. Nevertheless, he continued to state falsely in response to inquiries he received from the public following the October 3 press release and conference call that the damaged product was valued at \$10-20 million.

The October 8 Press Release

- 43. On October 8, 2003, an investment bank research analyst issued a research report with a Biovail sell rating (the "Report"). In the Report, the analyst questioned both Biovail's valuation of the product lost due to the accident as well as the Company's assertion of when title to the product transferred.
- 44. Howling received a copy of the Report on October 8 and he promptly forwarded to Melnyk and Crombie the portion of the Report questioning the value of the shipment involved in the truck accident, suggesting that someone in finance draft responses to the issues raised. Soon after, Howling forwarded the entire Report to Melnyk and Crombie.

- 45. Following circulation of the Report, other research analysts asked Howling many questions about the quantity of product on the truck, the value of that product, and the wide range of value Biovail had given on October 3.
- 46. Also on October 8, an employee at the Distributor called and e-mailed Howling in order to correct some of the misstatements in the October 3 press release and conference call. The e-mail, which Howling forwarded to Melnyk and Crombie, said that Biovail's conference call statement on when title to the product passed to the Distributor was "an incorrect statement, as the [agreement between Biovail and the Distributor] provides that title to and risk of loss with respect to the product would not have passed to [the Distributor] until the product was delivered to [the Distributor's] facility in the U.S.A." Howling assumed responsibility for speaking to the employee of the Distributor prior to issuing any further press releases on the subject.
- 47. Hours later while under fire from analysts and investors as a result of the Report Biovail issued a second press release that announced the recovery and salability of the product involved in the accident and "re-confirm[ed] that the sales value of these goods is within previously stated guidance." Melnyk dictated the October 8 press release, which both Crombie and Howling reviewed and edited prior to its issuance. The October 8 press release was issued by Howling's office, under his supervision, and his name appears on it as the contact person. Biovail issued this press release even though Howling had been unable to speak with the employee of the Distributor before the release was issued.
- 48. The October 8 press release was deliberately and materially false and misleading. Even though Melnyk, Crombie, Howling, and Biovail all knew or recklessly disregarded that the

truck accident had no impact on third quarter revenues, the October 8 press release was silent on that subject. This was a material omission.

49. Moreover, Melnyk, Crombie, Howling, and Biovail knew or recklessly disregarded that the statement in the October 8 press release reconfirming the October 3 guidance concerning the value of the product involved in the accident was materially false and misleading because they knew that the value in the October 3 press release was deliberately overstated.

October 10-15 Road Show

- 50. In the days immediately following October 8, there was a perception inside Biovail that management's credibility had been attacked by the Report on October 8. Biovail wanted to address these credibility concerns and other issues with investors, including any questions about Biovail's ability to meet anticipated market demand for Wellbutrin XL.
- 51. To this end, on October 10, 13, 14, and 15, 2003, Biovail executives Melnyk, Crombie, and Howling conducted a road show in New York, Boston, and other cities to meet with market analysts and investors. During the road show, the Biovail executives talked about, among other things, the matters discussed in the Company's October 3, 2003 press release.
- 52. The road show included a power point presentation prepared by Howling that repeated falsely that the truck accident's impact on Biovail's third quarter 2003 revenue was \$10 to \$20 million. In addition to the slides, the executives at the road show provided commentary and answered questions reiterating the false statements in the October 3 press release. At the time of these misstatements, Melnyk, Crombie, Howling, and Biovail all knew or deliberately disregarded that the statements attributing part of the third quarter revenue shortfall to the truck

accident were materially false and misleading. Melnyk, Crombie, Howling, and Biovail also knew or recklessly disregarded that the road show statements concerning the value of the product on the truck were materially false and misleading.

The Misstatements Were Never Fully Corrected

53. On March 3, 2004, in its annual earnings release Biovail finally acknowledged that the revenue associated with the product involved in the truck accident was only about \$5 million rather than the \$10 to \$20 million previously stated on October 3, 2003. Even this release, however, did not acknowledge that the truck accident had no impact on Biovail's third quarter revenues.

B. Material Misstatements Related to Pharmatech

- 54. In mid-2001, Biovail sought to increase net income by removing from its books the research and development costs associated with a key mid-term product pipeline. To achieve this goal, Biovail created a special purpose entity, Pharmaceutical Technologies Corp. (known as Pharmatech), to carry those costs.
- 55. Despite the fact that research and development costs were expected to be in the tens of millions of dollars, with some estimates as high as \$120 million, Pharmatech's sole shareholder, whom Biovail secured, invested only \$1 million in the company, of which \$350,000 was immediately refundable as a fee.
- 56. Biovail secured financing for Pharmatech from its own lender (the "Bank"), based on Crombie's assurances that, if at any time the Bank chose not to renew the Pharmatech financing, Biovail would likely purchase Pharmatech and retire the debt.

Filed 08/22/2008

- 57. Crombie and Biovail deliberately and fraudulently orchestrated the Pharmatech arrangement as a means to avoid recording on Biovail's books and records and reporting on its financial statements the expenses and liabilities related to the research and development of certain Biovail products. Crombie knew, and told the Bank, that it was probable that Biovail would repay Pharmatech's debt to the Bank when it first came due after one year, regardless of the outcome of the research and development at that point, if the Bank did not renew the financing. Crombie and Biovail understood that under those circumstances U.S. GAAP required Biovail to record Pharmatech's expenses and liabilities and to include them on its own financial statements.
- 58. Nevertheless, Crombie and Biovail deliberately did not recognize and record Pharmatech's liabilities or charge its research development costs to expense as incurred on Biovail's books and records and did not include them on Biovail's financial statements. Instead, Crombie intentionally misled Biovail's auditors as to the true nature of the arrangement in order to secure from the auditors an opinion letter supporting Biovail's accounting for the arrangement.

The Applicable Accounting Principles

- 59. The applicable U.S. GAAP guidance in Statement of Financial Accounting Standards No. 68, Research and Development Arrangements ("SFAS 68"), provides that an enterprise that is a party to a research and development arrangement that allows it to obtain the results of research and development funded partially or entirely by others must estimate and recognize the liability on its own books and records if the enterprise is obligated to repay any of the funds provided by the other parties, regardless of the outcome of the research and development. Under such circumstances, SFAS 68 also requires the enterprise to charge the research and development costs to expense as incurred.
- 60. Even in the absence of a written agreement or contract requiring repayment by the enterprise, SFAS 68 sets forth a presumption that the enterprise has an obligation to repay the other parties if surrounding conditions suggest that it is probable that the enterprise will repay any of the funds regardless of the outcome of the research and development. That presumption can be overcome only by substantial evidence to the contrary. "Probable" in this context means that repayment is likely.
- 61. SFAS 68 provides examples of circumstances under which there is a presumption of a repayment obligation, including, among others, that the enterprise has indicated an intent to repay all or a portion of the funds provided regardless of the outcome of the research and development.

The Agreements Between Biovail and Pharmatech

62. Pharmatech was incorporated in Barbados on June 29, 2001 and, on the same day, it entered into a Product Development and Royalty Agreement with Biovail's Barbados

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subsidiary, Biovail Laboratories, Inc. In this agreement, Pharmatech agreed to pay all the costs and expenses required to obtain regulatory approval of certain products in Biovail's midterm product pipeline, and Biovail granted Pharmatech a license to use the technologies necessary to develop the products.

- 63. Biovail also agreed to pay Pharmatech a royalty calculated as a percentage of the net sales of each successfully developed and approved product. Although the royalty payments would continue for ten years after each product's launch, Biovail could terminate the royalty obligation at any time upon thirty days notice and instead pay a contractually specified amount that increased over time depending on the date of the termination notice.
- 64. In a related Advisory Agreement, Biovail also agreed to guide Pharmatech in the development of the products.
- 65. The products included in the Pharmatech portfolio were those that could be launched within two to five years. The intention was to improve on drugs that were already in the market by providing new drug delivery formulations that could enhance effectiveness and increase patient compliance.
- 66. Several of the products were being developed to use controlled release technology that allowed for the gradual and predictable release of active ingredients over twelve or twenty four hours. Other products were to use the FlashDose drug delivery system, in which the product dissolves rapidly on the user's tongue.
- 67. Biovail had obtained the FlashDose technology in November 1999 by acquiring another pharmaceutical company for approximately \$250 million. That purchase was a significant acquisition and both the FlashDose and controlled release technologies were

important to Biovail. Although in June 2001, it was not certain that the FlashDose or controlled release technologies could be combined effectively and safely with any of the products in the Pharmatech portfolio, Biovail told the Bank that the products comprised its key mid-term product pipeline.

68. In connection with the agreement with Pharmatech, Biovail also entered into a Share Option Agreement with Pharmatech's sole stockholder. This agreement permitted Biovail to purchase all of the stockholder's Pharmatech shares at any time until December 31, 2006, in exchange for a fixed purchase price that ranged from \$1.25 million to \$5 million depending on the date Biovail exercised the share purchase option.

Pharmatech's Agreement with the Bank

- 69. Although Pharmatech agreed to pay the costs of developing the products, it had little working capital with which to do so. The sole stockholder's capital investment was just \$1 million and the new company had no sources of revenue and no assets other than the potential future royalty payments and the license from Biovail to use the FlashDose and controlled release technologies in developing the products.
- 70. To address this problem Crombie approached several potential lenders but ultimately only the Bank agreed to provide financing. Since the 1990's the Bank had served as Biovail's primary lender extending hundreds of millions of dollars in financing to Biovail through a credit facility.
- 71. In a June 29, 2001 agreement, the Bank agreed to extend credit to Pharmatech in the maximum aggregate amount of \$60 million for 364 days, at which time the outstanding debt would become due and payable. Pharmatech, however, could seek a 364-day extension of the

credit facility, which the Bank could grant or deny in its discretion. As collateral, Pharmatech granted the Bank a security interest in the Product Development and Royalty Agreement, including the potential future royalty payments and the license to use the crucial technology to develop the products. In the event of default, the Bank would also have the right to assign Pharmatech's rights under the agreement to a third party, including the right to continue development of the products using the FlashDose and controlled release technologies.

- 72. In connection with the financing, Biovail provided a comfort letter addressed to the Bank stating that, if Biovail exercised its share purchase option, Biovail would arrange to repay in full on or before June 30, 2004 any outstanding balance then due. Thus, the probability that Biovail would repay Pharmatech's debt to the Bank turned on the likelihood that Biovail would exercise its share purchase option if the Bank did not renew the loan after one year.
- 73. Crombie made clear to the Bank during the discussions about financing that Biovail probably would repay the Bank regardless of the outcome of the product development. Specifically, Crombie told the Bank that: (1) Biovail had a compelling business incentive to acquire Pharmatech and repay the loan because Biovail would want the royalties from any successfully developed products; (2) in any event, Biovail did not want its competitors acquiring access to the license to use the FlashDose (which Biovail had paid \$250 million to acquire) or controlled release technologies that Biovail had assigned to Pharmatech; and (3) the Bank had an effective "annual put" to Biovail, meaning that, when the credit facility came up for review after one year, if the Bank declined to extend the financing, the Bank could expect Biovail to acquire Pharmatech and repay the indebtedness.

The Auditors' Opinion Letter

- 74. In connection with the Pharmatech transaction, Biovail obtained from its auditors an opinion letter concerning the accounting implications of the transaction. Among other things, the opinion letter, dated June 29, 2001, analyzed the deal in light of SFAS 68. The letter contains a table summarizing in one column the factors specified in SFAS 68 and in a parallel column the information Crombie provided in June 2001 to the audit partner and other members of the audit team on each of those factors. Crombie knew that the auditors would rely upon that factual information in issuing their opinion, and they did rely on it.
- 75. Specifically, in order to secure the opinion letter from Biovail's auditors, in June 2001, Crombie made the following misstatements to the audit partner and other members of the audit team:
 - Crombie told the auditors that Biovail's management did not believe that it was
 probable that Biovail would repay the amounts being advanced and that the
 funding provided by others should not be recorded as a liability.
 - Crombie told the auditors that Biovail had not provided any explicit or implicit undertakings to any parties involved in the transaction to repay all or a portion of the funds provided.
 - Crombie told the auditors that Biovail's management did not currently believe
 that it was probable that it would choose to purchase the common shares of
 Pharmatech rather than incur any penalty.
- 76. Crombie also falsely stated during regular conversations in June 2001 with the audit partner and other members of the audit team that he gave no comfort to the Bank in regard to exercising any options and did not provide any guaranties, or puts, or protections, or anything of the like.

- 77. Crombie's statements to the auditors were materially false and misleading because he was telling the accountants the opposite of what he was contemporaneously telling the Bank. In particular, Crombie failed to tell the auditors that he had told the Bank that, in the event of a Pharmatech default, Biovail would have a compelling business incentive to exercise its option to acquire Pharmatech and repay the indebtedness to the Bank. Crombie also did not tell the auditors that he had told the Bank that the annual loan renewal mechanism was effectively an "annual put" to Biovail. Similarly, Crombie did not tell the auditors that he had told the Bank that Biovail would not want to see the technology license in which the Bank had taken a security interest fall into the hands of Biovail's competitors. These were material false statements and omissions.
- 78. Crombie was well aware of the U.S. GAAP requirements for research and development arrangements because of his involvement in Biovail's previous such arrangements. Crombie deceived the auditors because he specifically understood that the auditors would not issue the opinion letter regarding Pharmatech if he told them the truth.

Biovail's Purchase of Pharmatech When the Bank Did Not Renew the Financing

- 79. At the conclusion of the initial year of financing, in June 2002, the Bank extended Pharmatech's financing but only for six more months, until December 31, 2002. As early as October 2002, Biovail management began to conclude that the Bank would neither renew the credit facility on December 31, 2002 nor increase its limit. Finally, on December 24, 2002, Crombie learned definitively that the Bank would not extend any additional funds to Pharmatech.
- 80. Three days later, Biovail sent a letter notifying the Pharmatech stockholder that Biovail intended to exercise the purchase option. Consistent with the "put" representations

Crombie had made to the Bank, Biovail bought Pharmatech when the Bank decided not to extend additional financing, and repaid the Bank in full. Biovail's actions confirm that the Company's intention always was to exercise its purchase option and repay the Bank if the credit facility was not extended.

False and Misleading Public Filings

- 81. Biovail's interim financial statements for the quarter ended September 30, 2001 and for the nine months ended September 30, 2001 were furnished to the Commission on Form 6-K on November 13, 2001. Biovail's interim financial statements for the quarter ended March 31, 2002 were furnished to the Commission on Form 6-K on May 30, 2002. Biovail's interim financial statements for the quarter ended June 30, 2002 were furnished to the Commission on Form 6-K on August 29, 2002. On that date Crombie signed a certification stating the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.
- 82. Biovail's interim financial statements for the quarter ended September 30, 2002 were furnished to the Commission on Form 6-K on November 25, 2002. On that date Crombie signed a certification stating the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.
- 83. Biovail's annual report for the year ended December 31, 2001 was signed by Crombie and filed with the Commission on Form 20-F on May 17, 2002. Biovail's annual report for the year ended December 31, 2002 was signed by Crombie and filed with the

Commission on May 20, 2003. On that date, Crombie also signed a certification stating that the Form 20-F report "fairly presents, in all material respects, the financial condition and results of operations of the Company." Crombie and Biovail knew, or recklessly disregarded, that this representation was materially false and misleading.

- 84. As a direct result of Crombie's and Biovail's intentional failure to record on Biovail's books and records a total of approximately \$47 million in Pharmatech's expenses and more than approximately \$51 million in liabilities related to the research and development through September 30, 2002, Biovail's financial statements were materially misstated. In addition, during the fourth quarter of 2002, Biovail did not charge to expense as incurred more than \$10 million in additional Pharmatech expenses and did not timely recognize and record on Biovail's books and records additional related liabilities that Pharmatech incurred during that quarter.
- 85. Specifically, Biovail's financial reports were materially false and misleading in that they did not include Pharmatech's research and development expenses, causing: (1) net income to be overstated by approximately 50% in the third guarter 2001, 32% in the 2001 annual financial statements, 15% in the first quarter 2002, 18% in the second quarter 2002, and 16% in the third quarter 2002, and understated by approximately 17% in the 2002 annual financial statements; and (2) net income excluding certain charges to be overstated by approximately 25% in the third quarter 2001, 12% in the 2001 annual financial statements, 16% in the third quarter 2002, and 17% in the 2002 annual financial statements.
- 86. Biovail's balance sheets included in the financial reports also were materially false and misleading because they did not include Pharmatech's liability to the Bank, causing

Biovail's total liabilities to be understated by approximately 2% in the third quarter 2001, 11% at year-end 2001, 5% in the first quarter 2002, 5% in the second quarter 2002, and 7% in the third quarter 2002.

- 87. Crombie and Biovail knew, or recklessly disregarded, that the financial statements identified above were materially false and misleading.
- 88. During the period when Biovail's financial statements were intentionally and materially misstated as a result of the Pharmatech fraud, Biovail conducted a registered offering in which it sold 12.5 million of its common shares and raised gross proceeds of approximately \$587.5 million. The prospectus supplement for this offering, filed on November 15, 2001, incorporated by reference Biovail's intentionally and materially false and misleading financial statements for the nine months ended September 30, 2001, furnished to the Commission on the Company's Form 6-K dated November 13, 2001.
- 89. Crombie and Biovail knew, or recklessly disregarded, that Biovail's materially false and misleading financial statements for the nine months ended September 30, 2001, were incorporated by reference into the prospectus supplement dated November 15, 2001.

C. A Sham Bill and Hold Transaction in June 2003

90. In the second quarter of 2003, both product revenue and total revenue were below even the low end of Biovail's previously issued guidance for the quarter, and the Company was in danger of missing earnings expectations for the first time in its history. In particular, Biovail had not sold any Wellbutrin XL, a drug that analysts considered crucial to the Company's health and whose sales potential had led some analysts to issue a buy recommendation for the Company.

91. Rather than acknowledge the Company's poor performance that quarter, Crombie, Miszuk, and Biovail fraudulently and improperly recognized and recorded approximately \$8 million in additional revenue from a phony sale of Wellbutrin XL. As a result, for the quarter ended June 30, 2003, Biovail's net loss was intentionally and materially understated by approximately 80% in its interim financial statements that Biovail furnished to the Commission on Form 6-K on August 29, 2003. Moreover, by recognizing the \$8 million in revenue from the phony sale in the second quarter of 2003, Biovail was able to avoid reporting a decrease in overall product revenue relative to the second quarter of 2002, which analysts would have considered a bad trend.

Biovail's Wellbutrin XL Agreement

- 92. Through subsidiaries, Biovail and the Distributor entered into a Development, License and CoPromotion Agreement in 2001. Pursuant to the agreement, and subject to FDA approval, Biovail was to manufacture Wellbutrin XL and sell it to the Distributor, which would distribute the product to third-party purchasers. The agreement required Biovail to produce Wellbutrin XL to be used for two purposes: (1) as sample product that Biovail would deliver in bulk to the Distributor and that the Distributor would package and distribute to physicians as a promotional tool; and (2) as trade product that Biovail would package in bottles labeled in accordance with the FDA's requirements and that the Distributor would sell at a commercial price upon FDA approval.
- 93. As modified in December 2002, the agreement provided different prices for the differing dosages of sample product and trade product. Biovail sold sample pills to the Distributor at fixed prices per tablet, effectively at cost and, at the start of the product launch, at a

loss. Biovail's Wellbutrin XL revenues for trade product were tied to the Distributor's net revenues from its sales to third parties. The agreement provided that Biovail would invoice trade product shipped to the Distributor at a fixed percentage of the Distributor's estimated net sales revenues and the invoicing percentage would rise as the Distributor's actual net sales increased over time. To the extent that the Distributor's estimate of its net sales revenues was different from the actual net sales revenue, the agreement contemplated a quarterly reconciliation process.

94. The FDA issued a letter on June 26, 2003 stating that Wellbutrin XL was "approvable," which meant that the FDA required further information before the new drug application could be approved. Among other things, the FDA's June 26 letter requested revised draft labeling for the product. The FDA did not finally approve Wellbutrin XL until August 29, 2003.

Biovail's Need to Generate Trade Product Revenue in June 2003

- 95. On February 7, 2003 Biovail published earnings guidance for its fiscal year 2003. It projected second quarter earnings per share between \$0.43 and \$0.50, third quarter earnings per share between \$0.58 and \$0.68, and annual sales of Wellbutrin XL of between \$75 million and \$150 million.
- 96. Wellbutrin XL was a key component of these earnings projections. It was widely expected that Wellbutrin XL would be the most significant product launch in the Company's history. The product, however, could not launch until it received FDA approval. When, by early June 2003, the FDA still had not yet approved Wellbutrin XL, Biovail executives became concerned because it was clear that Biovail would not meet its second quarter earnings projections unless it sold Wellbutrin XL trade product by June 30.

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- 97. Although Biovail needed to produce prior to approval enough Wellbutrin XL trade product to enable the Distributor to launch the product promptly, it was risky to manufacture too many pills before the FDA had determined as part of the approval process what the product's shelf life would be because the Distributor could return stale trade pills to Biovail. Sample product, however, because it would be given away rather than sold, could be distributed up until expiration.
- 98. In April and May 2003 the Distributor submitted purchase orders for the delivery of Wellbutrin XL sample pills in June and for delivery of trade product (contingent on FDA approval of the trade product packaging) in July.
- 99. There were two reasons why the Distributor sought delivery of sample pills before trade pills: (1) under the agreement, the Distributor was responsible for packaging sample pills and wanted sufficient quantities on hand early so it could prepare for the launch; and (2) there was a risk that trade pills could expire unused if they were produced too early.
- 100. By the middle of June 2003, Biovail had not filled the Distributor's pending orders for sample product. At the time, Biovail was experiencing manufacturing problems and, as a result, was unable to manufacture sufficient quantities to fill the sample orders. In addition, filling sample orders generated no income for Biovail. If Biovail had invoiced and shipped the inventory as samples during June, it would have sustained a loss because the cost of goods sold exceeded the contractual sample prices.

Crombie's Demand for a Trade Product Order in June

101. Even though Crombie knew about the production problems, he complained in a June 19, 2003 letter to the Distributor that Biovail needed the Distributor to place an order for

trade product for June delivery "so that Biovail could be assured that it could book the revenue associated with those shipments [of trade product] in Q2 of 2003." He proposed in his letter to sell to the Distributor as trade product "all of our current production" of Wellbutrin XL.

- 102. The Distributor acquiesced in Crombie's demand for a June order for trade product in view of Biovail's threat to turn its manufacturing capacity to other products, since that could have caused a delay in the Wellbutrin XL launch.
- 103. On June 20, 2003, the Distributor placed an order for 27.1 million tablets of trade product. Since FDA approval was still pending, Biovail could not label the product so the Distributor agreed to let Biovail hold the product awaiting FDA approval and packaging. Although Biovail had not manufactured enough pills to meet the order, Biovail purported to earmark the entire then-existing inventory of Wellbutrin XL in its warehouse, approximately 18 million pills, to fill this "bill and hold" order.
- 104. On June 30, 2003, Biovail invoiced the Distributor approximately \$8 million for the product, and recorded a sale at a price that was slightly reduced from the usual trade prices to reflect that the packaging would not be done or invoiced until after FDA approval. The parties did not agree, however, on a fixed schedule for delivery of the product because the date of FDA approval was not yet known.

Applicable Accounting Principles

105. Under U.S. GAAP, revenue may be recognized when it is realized or realizable and earned. Among other things, U.S. GAAP requires that the seller complete its performance under the contract, which in this case required that Biovail (1) manufacture the Wellbutrin XL pills; and (2) deliver those pills to the Distributor; (3) at a fixed or determinable price.

- 106. Ordinarily, revenue may be recognized only when delivery of the product by the seller to the buyer has occurred. Under certain limited circumstances a company may recognize revenue even before it has shipped the product. This type of transaction is commonly known as a "bill and hold transaction."
- 107. A legitimate bill and hold transaction permits revenue recognition before delivery provided the following additional criteria under U.S. GAAP are met:
 - (a) The risk of ownership must have passed to the buyer;
 - (b) The customer must have made a fixed commitment to purchase the goods, preferably reflected in written documentation;
 - (c) The buyer, not the seller, must request that the transaction be on a bill and hold basis. The buyer must have a substantial business purpose for ordering the goods on a bill and hold basis;
 - (d) There must be a fixed schedule for delivery of the goods. The date for delivery must be reasonable and must be consistent with the buyer's business purpose (e.g., storage periods are customary in the industry);
 - (e) The seller must not have retained any specific performance obligations such that the earnings process is not complete;
 - (f) The ordered goods must have been segregated from the seller's inventory and not be subject to being used to fill other orders; and
 - (g) The goods must be complete and ready for shipment.
- 108. The requirements of U.S. GAAP are summarized in Staff Accounting Bulletin No. 101 Revenue Recognition in Financial Statements ("SAB 101"). The purpose of these requirements is, in part, to prevent companies from selling the same product twice which is, among other things, what Biovail did here.
- 109. At the time of the transaction, Crombie and Miszuk both reviewed SAB 101 and understood the requirements under U.S. GAAP for a valid bill and hold transaction. This was a

Filed 08/22/2008

unique transaction for Biovail, which had not previously made any sales on a bill and hold basis. Despite their unfamiliarity with this type of transaction, Crombie and Miszuk did not discuss the bill and hold transaction with the Company's independent auditors at the time of the transaction to confirm that the revenue recognition requirements were properly met. Nor did they discuss this transaction with any of the chartered accountants who worked for the Company or the subsidiary of the Company on whose books the transaction was recorded.

One requirement for bill and hold transactions that was plainly and deliberately 110. flouted was the requirement that the ordered goods be segregated from the seller's inventory and not be subject to being used to fill other orders. Here, the goods supposedly sold in the sham bill and hold transaction constituted all of Biovail's inventory at that time. Consequently, there was no real segregation of Wellbutrin XL at Biovail's warehouse. Moreover, these pills were very soon thereafter designated by Miszuk and Crombie to fill the Distributor's pending orders for sample product and were shipped with new invoices at different and much lower prices – the sample prices.

The Pills Switch

111. The pills that Biovail was required to segregate to fill the June 30 bill and hold transaction were not fungible with later-produced pills because they were subject to an earlier expiration date. Although no one knew prior to FDA approval what the exact expiration date for trade product would be, Crombie and Miszuk believed in June that all of the tablets then in Biovail's inventory – which were supposedly sold to the Distributor in the purported bill and hold transaction – were already too old for trade use. To avoid potential returns of such stale pills by the Distributor, and in an attempt to fill the Distributor's orders for sample pills that had

been pending since April, Crombie and Miszuk, before the close of Biovail's second quarter books (and no later than mid-July), designated for shipment to the Distributor as sample product the very same pills that Biovail supposedly had designated and segregated for the purported June 30 bill and hold transaction. Thereafter, Crombie and Miszuk invoiced and shipped these same pills at the lower sample price instead of the higher trade price reflected on the original June 30 invoices and the Company's books. In this way, Crombie and Miszuk sold the same pills twice, at two different prices, to fill two different orders.

- 112. Crombie and Miszuk then invented a rationale by which Biovail purportedly could still recognize the trade sale revenue in the second quarter. They decided to replace the pills that would now be shipped as sample pills at the lower sample prices with newer pills that would now purport to be the subject of the June 30 sale.
- 113. Crombie's and Miszuk's scheme was promptly implemented. By July 18, Biovail sent the Distributor various schedules showing that Biovail intended to ship to the Distributor under sample invoices and at the lower sample prices the very same pills that were the subject of the June 30 trade sale invoices at the higher, trade prices. And Crombie and Miszuk ultimately shipped these pills to the Distributor under new invoices at sample prices. The original June 30 trade sale invoices were never paid and eventually were withdrawn through issuance of credit memos.
- 114. As of mid-July, however, as Miszuk and Crombie both knew, Biovail had not yet manufactured the additional pills needed to replace the pills purportedly segregated for the June 30 trade sale. Thus, there were not sufficient pills in existence at any time prior to the close of the second quarter books to apply to the June 30 trade sale once Crombie and Miszuk designated

all of the pills then in existence to fill the sample orders. Accordingly, Biovail never really implemented a pill-for-pill substitution to replace the purportedly segregated pills with newly manufactured pills. Miszuk and Crombie knew this prior to the close of Biovail's second quarter books and records or were reckless in not knowing this.

115. Crombie and Miszuk did not discuss with Biovail's independent auditors their scheme to replace the supposedly segregated pills. They did not seek any guidance from them as to whether the requirements of U.S. GAAP for revenue recognition generally or for a bill and hold transaction could be met by replacing the pills. Instead, in meetings with Biovail's independent auditors on July 23 and July 25, Crombie and Miszuk led the auditors to believe that a shipment of trade product had actually occurred on June 30, which was not true. Miszuk also falsely told the auditors in connection with their quarterly review that pricing on the June 30 trade product sale was fixed even after he and Crombie had decided to ship the same pills supposedly sold in that transaction to the Distributor at the lower sample prices. Crombie and Miszuk similarly did not discuss with the chartered accountants who worked for the Company (or the Company's subsidiary on whose books the transaction was recorded) their scheme to replace the segregated pills.

Intentionally and Materially False and Misleading Public Statements

- 116. In late July, Biovail closed its books on the second quarter still recognizing improperly the approximately \$8 million in revenue in connection with the June 30 trade product sale. On July 29, 2003, Biovail issued an earnings release for the quarter ended June 30, 2003 that both Crombie and Miszuk reviewed before its issuance. On the same day, Biovail conducted a conference call with analysts to discuss the Company's financial results for the second quarter.
- Company announced its second quarter results on July 29, 2003, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, that the requirements under U.S. GAAP for revenue recognition for a bill and hold transaction were not satisfied with respect to the Wellbutrin XL trade product sale transaction that purportedly occurred on June 30, 2003. Specifically, Crombie, Miszuk, and Biovail knew, or recklessly disregarded, among other things, that: (a) as of June 30, 2003 there was no fixed schedule for delivery of the goods because FDA approval for Wellbutrin XL still had not occurred; (b) the Distributor had not agreed to pay the higher trade price for product it used as sample product; (c) the pills supposedly segregated for the June 30, 2003 trade sale comprised all of Biovail's Wellbutrin XL tablets as of June 30, 2003,; and (d) Biovail had not manufactured any or enough other pills as of June 30 or as of the date when Biovail's second quarter books were closed in July to replace the supposedly segregated pills that Crombie and Miszuk designated for shipment to the Distributor to fill the Distributor's other pending orders for sample product at the lower sample prices.

- 118. The second quarter earnings announced by Biovail appeared to meet the Company's guidance for the second quarter. As a direct result of the improper recognition of revenue on the phony bill and hold transaction, the July 29, 2003 earnings release was intentionally and materially false and misleading. Specifically, the earnings release understated the Company's net loss for the quarter by approximately 80% and overstated the Company's net income (excluding acquired R&D) for the quarter by about 5%.
- Howling said, "Additionally, in the second-quarter 2003, approximately \$8 million of Wellbutrin XL was supplied to [the Distributor]." Although Crombie knew or recklessly disregarded at the time of the conference call that the requirements under U.S. GAAP for revenue recognition for a purported bill and hold transaction were not satisfied, he omitted to correct Howling's misstatement.
- 120. During August, after the Distributor began receiving the shipments of sample product, the Distributor notified Biovail that, because the August sample invoices identified the same tablets that were associated with the June 30 trade invoices, the Distributor would not process the June 30 trade invoices at that time. This message was forwarded to Crombie and Miszuk on August 14, 2003.
- 121. By no later than August 29, 2003, Miszuk, Crombie, and Biovail knew or recklessly disregarded, among other things, that during August the Distributor had refused to process the June 30 invoices for the trade product sale because Biovail was shipping the same pills under sample invoices at the lower sample prices.

- 122. Nevertheless, on August 29, 2003, the Company furnished to the Commission on Form 6-K Biovail's second quarter financial statements that were intentionally and materially false and misleading. Specifically, as a direct result of the improper recognition of revenue on the phony bill and hold transaction, the Company's net loss was understated by approximately 80%.
- 123. Miszuk signed this Form 6-K and Crombie also signed a statement that the Form 6-K report "fairly presents, in all material respects, the financial condition and results of operations of the Company." At that time, Crombie, Miszuk, and Biovail knew, or recklessly disregarded that the financial statements, and Crombie's statement, were intentionally and materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.
- 124. The next business day, on September 1, 2003, Biovail issued two credit memos to the Distributor voiding the two unpaid June 30 trade invoices.
- 125. On May 14, 2004, Biovail furnished to the Commission on Form 6-K/A restated financial statements for the quarter ended June 30, 2003. This restatement corrected material misstatements resulting from the previously unrecorded and unreported foreign exchange loss discussed below. But in this 2004 amendment, Biovail continued to reflect the approximately \$8 million in revenue and about \$4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial statements to understate net loss by about 45%. Miszuk signed this Form 6-K/A and Crombie also signed a statement that the Form 6-K/A report "fairly presents, in all material respects, the financial condition and results of operations of the

Company." At that time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the financial statements, and Crombie's statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale included in the second quarter financial statements was not in accordance with U.S. GAAP.

126. Biovail's annual report for the year ended December 31, 2003 was signed by Crombie and filed with the Commission on May 14, 2004. This report presents restated second quarter results as they appear in the Form 6-K/A furnished to the Commission the same day, and like that Form 6-K/A, these restated results continued to reflect the approximately \$8 million in revenue and about \$4 million in earnings from the phony June 30 bill and hold transaction, causing the restated financial results for the second quarter of 2003 set forth in the Form 20-F to understate net loss by about 45%. On May 14, 2003, Crombie also signed a certification stating, among other things, that, based on Crombie's knowledge: (1) 'this [Form 20-F] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;" and (2) "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report[.]" At that time, Crombie, Miszuk, and Biovail knew or recklessly disregarded that the Form 20-F, and Crombie's statement, were materially false and misleading because the revenue recognition on the purported June 30 trade product sale and included in the second quarter financial statements was not in accordance with U.S. GAAP.

Crombie's and Miszuk's Deception of Biovail's Auditors

- 127. Not only did Biovail, Crombie, and Miszuk not seek advice and guidance from Biovail's auditors concerning whether the bill and hold accounting was proper, but Crombie and Miszuk also made material misstatements and omissions about the June trade order to the auditors in connection with both the second quarter review and the 2003 annual audit.
- 128. In connection with the quarterly review, by July 22, Miszuk told the auditors that pricing was fixed on the June trade order even though, by July 18, he and Crombie already had designated for shipment as sample pills at the lower sample prices the pills purportedly segregated for the bill and hold sale.
- 129. Also during the quarterly review, Crombie discussed with the auditors their request for a confirmation about fixed pricing. In their communications with Crombie and Miszuk on at least July 23 and July 25, the auditors referred to the June transaction as a "shipment," showing their belief that actual delivery had occurred. Neither Crombie nor Miszuk corrected this misunderstanding. They did not tell the auditors that the Company had treated the June trade product sale as a bill and hold transaction. Similarly, neither Crombie nor Miszuk told the accountants in July that they had decided to use the pills originally identified on the "bill and hold" invoices to fill the Distributor's sample orders at the lower sample prices. They also did not tell the accountants that Biovail did not have sufficient product on hand to fill both the trade order and the outstanding sample orders,
- 130. Miszuk and Crombie similarly failed to tell the auditors during August that the Distributor was refusing to pay the June invoices because Biovail had shipped to the Distributor the very same pills under sample invoices, that the available pills were aged and best used as

samples to avoid returns, and that the Distributor did not agree to pay trade prices if it used the pills as sample product. Crombie also falsely told the auditors in February 2004 during the year-end audit that the Distributor's non-payment of the invoices in connection with the June 2003 transaction was part of a larger problem involving the Distributor's failure to pay Biovail's invoices and had nothing to do with the specific bill and hold transaction.

- circulated to Biovail executives and auditors which purported to provide an overview of the Company's quarterly financial performance, including both narrative and financial statements. Prior to the circulation of the management report to Biovail's auditors on July 25 and 30, 2003, Miszuk reviewed and approved the content of the report, which he knew the auditors used as part of their review process. By including approximately \$8 million in revenue associated with the purported June 30 trade product sale, Biovail's July 25 and 30, 2003 second quarter 2003 management reports were materially false in two ways: (1) they overstated income and (2) both falsely asserted that "[a]ll figures contained in [the] report [were] in accordance with U.S. GAAP."
- January and February 2004 in connection with the year-end audit —after discovering the credit memos that reversed the June 2003 transaction did the accountants first learn that Biovail had recorded the June 30 transaction as a bill and hold. Even then, neither Miszuk nor Crombie told the auditors that Biovail had shipped and invoiced as sample product in August the pills supposedly segregated for the bill and hold transaction in June.

Crombie and Miszuk also misled the auditors in early 2004 about the true reason 133. for the September 1, 2003 credit memos. They told them that Biovail had credited out the June 30 invoices so that it could issue new invoices that included packaging costs. The truth was that the Distributor had refused to pay the June 30 invoices and two sets of invoices could not have duplicate lot numbers on them.

Material Misstatements Concerning Unrecognized Foreign Exchange Loss D.

- Concurrent with its improper attempt to record unearned revenue through the 134. sham bill and hold transaction, Biovail also sought to conceal its weak second quarter 2003 performance by intentionally failing to record in the second quarter of 2003 approximately \$3.9 million in additional losses due to foreign currency fluctuations.
- In December 2002 Biovail's Barbados subsidiary acquired from the 135. Wellbutrin XL Distributor the Canadian rights to two pharmaceutical products. Biovail paid a portion of the consideration in cash and borrowed the balance from the Distributor. Although the currency for the transaction was Canadian dollars, Biovail's functional currency is the U.S. dollar, and Biovail reports its financial results in U.S. dollars.
- The U.S. GAAP guidance applicable to the translation of foreign currency 136. statements is Statement of Financial Accounting Standards No. 52, Foreign Currency Translation, which provides: "All elements of financial statements shall be translated by using a current exchange rate. For assets and liabilities, the exchange rate at the balance sheet dates shall be used." Consistent with this guidance, in its 2002 year-end financial statements filed with the Commission on Form 20-F on May 21, 2003, Biovail correctly reported the outstanding loan obligation in U.S. dollars by applying the then-current exchange rate.

- 137. On March 31, 2003, the date of Biovail's first quarter balance sheet, the Canadian dollar had strengthened against the U.S. dollar since December 31, 2002. Instead of applying the exchange rate current as of March 31 to translate the outstanding balance due on the loan from Canadian to U.S. dollars, Biovail translated the outstanding balance using the same exchange rate that it had applied in its financial statements for the year ended December 31, 2002. As a result, Biovail's financial statements for the first quarter of 2003, furnished to the Commission on Form 6-K on May 30, 2003, overstated net income by about 9%.
- 138. In Biovail's financial statements for the second quarter of 2003, the Company repeated the error it had made in the first quarter and again translated the remaining balance into U.S. dollars using the same exchange rate that Biovail had applied in its annual financial statements for the year ended December 31, 2002. This time, however, the error was not inadvertent.
- 139. On July 8, 2003, early in the quarterly closing process, the controller for the Barbados subsidiary and Biovail's senior director of legal accounting, both chartered accountants who reported to Miszuk, told Miszuk in an e-mail that the remaining outstanding balance should be adjusted to reflect the June 30 exchange rate and that doing so would generate an additional cumulative foreign exchange loss of approximately \$9 million. The senior director of legal accounting noted in the e-mail that the additional foreign exchange loss was going to cause concern at the senior management level. Miszuk reviewed the e-mail and responded to it stating: "can we discuss this on Thursday can I see some analysis on this."
- 140. Despite this clear identification of the issue, Miszuk and Biovail did not record this additional foreign exchange loss, which Miszuk knew, or recklessly disregarded, would have

negatively affect Biovail's second quarter financial results (and also would have nullified a significant portion of the earnings Biovail planned to recognize from the sham bill and hold transaction). Moreover, the Company would have been required to restate its first quarter financial results, something Miszuk did not want to do.

- 141. As a result, Biovail's interim financial statements for the quarter ended June 30, 2003, furnished to the Commission on Form 6-K on August 29, 2003, were materially misstated, intentionally or recklessly. Specifically, for the three-month period ended June 30, 2003, the Company's net loss was understated by about 80%, or approximately \$3.9 million, and for the six-month period ended June 30, 2003, the Company's net income was overstated by 18%, or approximately \$9.3 million. Although Miszuk knew about or recklessly disregarded the exchange rate translation error, he nevertheless signed this Form 6-K.
- them for circulation to, among others, the Company's outside auditors during their second quarter review. These reports present results for both the three months and six months ended June 30, 2003. As a result of Biovail's failure to record correctly the foreign exchange loss, the three-month period is misstated in the reports by about \$3.9 million and the six-month period, which includes the misstatement for the quarter ended March 31, 2003, is misstated by approximately \$9.3 million. These reports also asserted falsely that all figures were in accordance with U.S. GAAP. Miszuk knew, or recklessly disregarded, that the financial statements in the management reports as well as that representation were materially false and misleading.

- during the third quarter of 2003 prior to Biovail furnishing its Form 6-K to the Commission on August 29. He acknowledged the loss in previous quarters and sought a hedging strategy. Notwithstanding his awareness of the additional loss in the first two quarters of the year, Miszuk took no steps to correct the misstated quarterly reports or even to correct the problem going forward. As a result, Biovail's third quarter financial results were also incorrect because the Company understated its quarterly net income by approximately \$3.1 million, or 19%. For the nine months ended September 30, 2003, the resulting cumulative overstatement of net income was approximately \$6.2 million (the \$9.3 million overstatement for the first two quarters less \$3.1 million understatement in the third quarter), or about 9%.
- 144. In its March 3, 2004 year-end and fourth quarter 2003 earnings release, Biovail announced that, "in the course of preparing its financial statements for the fourth quarter and the full year 2003, the Company determined that U.S. GAAP requires that the Canadian dollar liability be translated at current rates." The release was false and misleading in that Miszuk and Biovail first learned about the issue the previous July.
- 145. On May 14, 2004, Biovail furnished to the Commission, on three Forms 6-K/A, its restated interim financial statements for the first, second, and third quarters of 2003. The restatements show that, as a result of the failure to record properly the foreign exchange loss, Biovail's net income was overstated by about 9% for the first quarter, its net loss was understated by 80% for the second quarter, and its net income was understated by about 19% for the third quarter.

- 146. Like the March 3 earnings release, each Form 6-K/A contained a statement implying that the error was discovered during the 2003 annual audit: "During the course of the preparation of its annual consolidated financial statements, the Company determined that it had applied an inappropriate exchange rate to a Canadian dollar denominated long-term obligation." Miszuk had learned about the problem much earlier, in July 2003, but on May 14, 2004 he nevertheless signed each of these Forms 6-K/A, which Biovail furnished to the Commission the same day.
- 147. The cumulative impact of the misstated foreign exchange loss and the improperly recognized bill and hold revenue was a total understatement of net loss in the second quarter 2003 financial statements by approximately 89%. As a result of Crombie's and Miszuk's misconduct in connection with these two matters, Biovail improperly reported EPS of \$0.52 in the second quarter, beating consensus analyst expectations (\$0.47) by more than 10%. This was one of the few positive (albeit false) financial data points that Biovail reported in the second quarter of 2003 and it helped to salvage an otherwise weak quarter.

E Melnyk Failed to Disclose his Full Biovail Share Ownership

148. As a holder of greater than 5% of Biovail's outstanding shares, Melnyk was under a legal obligation to make certain public disclosures concerning his stock ownership under Section 13(d) of the Exchange Act and related rules. On September 23, 1996, Melnyk settled four Cayman Island trusts and funded the trusts with Biovail shares that were previously held by him personally, directly or indirectly. The Biovail shares transferred to the trusts represented approximately 19% of the outstanding shares of Biovail at that time. Melnyk continued to exercise control over the Biovail shares in the trusts. Nevertheless, he did not include in his

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public filings pursuant to Section 13(d) of the Exchange Act and related rules any mention of his beneficial ownership of the Biovail shares in the trusts.

Melnyk Had a Beneficial Interest in the Shares Held in the Trusts

- By 2003, the four trusts' holdings constituted just under eight percent of the Biovail common shares outstanding and approximately 30 percent of Melnyk's total Biovail holdings. Each of the four trusts had a "protector."
- 150. The controller of Biovail's Barbados subsidiary was separately paid by Melnyk to assist him with issues concerning the trusts, and assumed the role of protector of one of the trusts beginning in 2002. She also was a liaison between Melnyk and the trustees of all four trusts as well as the account representatives on the trusts' brokerage accounts. She conferred with Melnyk regularly about the trusts, including their transactions in Biovail securities.
- Although the trust documents provide that trustees and the protective committees 151. have investment power over trust assets, including the Biovail shares, Melnyk continued to make decisions concerning both the trusts and the shares they held.
- Melnyk decided where the brokerage accounts for the trusts would be held and 152. hence where the Biovail stock would be held - and how that Biovail stock would be voted in Company elections. Melnyk similarly directed when and how the trusts would buy and sell Biovail stock.
- In addition, Melnyk caused the trustees to sell Biovail stock to fund over 153. \$100 million in loans to him from the trusts that he has never repaid. Melnyk knew or should have known that his requests for loans in certain circumstances could reasonably be expected to trigger sales by the trusts of Biovail securities.

154. Melnyk was aware of trading by the trusts in Biovail securities and he could, as a practical matter, exercise control over it and could have stopped it if he wished.

Melnyk Did Not Disclose His Ownership of the Trust Shares in any of his Filings Pursuant to Section 13(d) of the Exchange Act

155. As beneficial owner of more than 5% of the Biovail shares outstanding, Melnyk filed his first Schedule 13-D with the Commission on March 30, 1994. He has since filed twenty three amended Schedules 13-D through January 17, 2007. In none of these filings did he disclose his beneficial interest in the Biovail shares held by the trusts, or any material increases or decreases in the trusts' holdings.

F. Biovail's Violations of Rule 302(b) of Regulation S-T

156. Biovail electronically filed with the Commission certain annual reports on Forms 20-F. The Commission staff requested the Company to furnish to the staff manually signed signature pages or other documents in which the signatories to such electronic filings acknowledged or otherwise adopted their signatures that appear in typed form within the electronic filings. The Company has not complied with that request and is unable to do so.

FIRST CLAIM FOR RELIEF Violations of Section 17(a) of the Securities Act

- 157. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 156.
- 158. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities, by the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have employed or are employing devices, schemes and artifices to defraud.

- the use of the means and instruments of transportation and communication in interstate commerce or by the use of the mails, directly and indirectly, have obtained or are obtaining money and property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, and have engaged or are engaging in transactions, practices or courses of business which have operated or would operate as a fraud and deceit upon investors.
- 160. Crombie and Biovail, directly or indirectly, singly or in concert, in the offer and sale of securities described herein, have made untrue statements of material fact, or have omitted to state material facts. Among other things, the materially misleading statements or omissions pertained to Pharmatech's expenses and liabilities related to the research and development of certain Biovail products that Crombie and Biovail intentionally did not include on Biovail's interim financial statements for the period ended September 30, 2001, which Biovail incorporated by reference into the prospectus supplement dated November 15, 2001.
- 161. Crombie and Biovail knew or were reckless in not knowing of the activities described above.
- 162. By reason of the foregoing, Crombie and Biovail have violated, and unless enjoined will again violate, Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

SECOND CLAIM FOR RELIEF Violations of and Aiding and Abetting Violations of Section 10(b) of the Exchange Act and Rule 10b-5

- 163. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 162.
- 164. Defendants, singly or in concert, in connection with the purchase and sale of securities, directly or indirectly, by the use of the means and instrumentalities of interstate commerce or of the mails, have employed or are employing devices, schemes and artifices to defraud; have made or are making untrue statements of material fact and have omitted or are omitting to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and have engaged or are engaging in acts, practices and courses of business which have operated or would operate as a fraud and deceit upon investors, in violation of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].
- 165. Defendants knew or were reckless in not knowing of the activities described above.
- 166. By reason of the foregoing, Defendants have violated, and unless enjoined will again violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5)].
- 167. By reason of the foregoing, Melnyk, Crombie, Miszuk, and Howling aided and abetted Biovail's violations of, and unless enjoined will again aid and abet violations of, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. §240.10b-5].

THIRD CLAIM FOR RELIEF Violations of Section 13(b)(5) of the Exchange Act

- 168. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 167.
- Crombie and Miszuk, directly or indirectly, singly or in concert, knowingly 169. circumvented or knowingly failed to implement a system of internal accounting controls and knowingly falsified, directly or indirectly, or caused to be falsified books, records and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].
- By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(b)(5)].

FOURTH CLAIM FOR RELIEF Violations of Rule 13b2-1 of the Exchange Act

- 171. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 170.
- 172. Crombie and Miszuk, directly or indirectly, singly or in concert, falsified or caused to be falsified the books, records, and accounts of Biovail that were subject to Section 13(b)(2)(A) of the Exchange Act [15 U.S.C. § 78m(b)(2)(A)].
- 173. By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Rule 13b2-1 of the Exchange Act [17 C.F.R. § 240.13b2-1].

FIFTH CLAIM FOR RELIEF Violations of Rule 13b2-2 of the Exchange Act

- The Commission realleges and incorporates by reference herein each and every 174. allegation contained in paragraphs 1 through 173.
 - 175. Crombie and Miszuk were officers of Biovail at all relevant times.
- 176. As described above, Crombie and Miszuk, directly or indirectly, singly or in concert, made or caused to be made materially false or misleading statements, or omitted to state or caused another person to omit to state material facts necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading to an accountant, in connection with (i) audits, reviews and examinations of the financial statements of Biovail required to be made pursuant to Commission regulations, and (ii) the preparation and filing by Biovail of documents and reports required to be filed with the Commission.
- By reason of the foregoing, Crombie and Miszuk have violated, and unless enjoined will again violate, Exchange Act Rule 13b2-2 [17 C.F.R. § 240.13b2-2].

SIXTH CLAIM FOR RELIEF

Violations of and Aiding and Abetting Violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, and 13a-16

- The Commission realleges and incorporates by reference herein each and every 178. allegation contained in paragraphs 1 through 177.
- 179. Biovail did not file with the Commission such financial reports as the Commission has prescribed, and Biovail did not include, in addition to the information expressly required to be stated in such reports, such further material information as was necessary to make the statements made therein, in light of the circumstances in which they were made, not

misleading, in violation of Section 13(a) and of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

180. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-16].

SEVENTH CLAIM FOR RELIEF Violations of and Aiding and Abetting Violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act

181. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 180.

182. Biovail did not:

- make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflected the transactions and dispositions of its assets; and
- b. devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:
 - i. transactions were executed in accordance with management's general or specific authorization;
 - ii. transactions were recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and to maintain accountability for assets;

- iii. access to assets was permitted only in accordance with management's general or specific authorization; and
- iv. the recorded accountability for assets was compared with the existing assets at reasonable intervals and appropriate action was taken with respect to any differences, in violation of Sections 13(b)(2)(A) and 13(B)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].
- 183. By reason of the foregoing, Biovail violated, and Crombie and Miszuk have aided and abetted Biovail's violations of, Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

EIGHTH CLAIM FOR RELIEF Violations of Rule 13a-14

- 184. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 183.
- 185. Crombie knew or recklessly disregarded that his certifications of Biovail's 2002 and 2003 Forms 20-F were materially false and misleading.
- 186. By reason of the foregoing, Crombie has violated, and unless enjoined will again violate, Rule 13a-14 [17 C.F.R. § 240.13a-14].

NINTH CLAIM FOR RELIEF Violations of Section 13(d) of the Exchange Act and Rules 13d-1 and 13d-2

- 187. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 186.
- 188. The common stock of Biovail at all relevant times was registered pursuant to Section 12 of the Exchange Act [15 U.S.C. § 781].
- 189. Pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2], persons who are directly or indirectly the beneficial owners of more than five percent of the outstanding shares of a class of voting equity securities registered under the Exchange Act are required to file a Schedule 13D within ten days of the date on which their ownership exceeds five percent, and to notify the issuer and the Commission of any material increases or decreases in the percentage of beneficial ownership by filing an amended Schedule 13D. The Schedule 13D filing requirement applies both to individuals and to two or more persons who act as a group for the purpose of acquiring, holding, or disposing of securities of an issuer.
- 190. As described above, Melnyk was at all relevant times a beneficial owner of more than 5 percent of Biovail's shares. In addition to the shares that he held in his own name, as a result of his investment and voting authority over the shares held in the trusts, he also was a beneficial owner of those Biovail shares.
- 191. Melnyk and the trusts also were sufficiently interrelated that they constituted a group for the purposes of the Section 13(d) and the Schedule 13D filing requirement.

- 192. Accordingly, Melnyk was under an obligation to file with the Commission true and accurate reports with respect to his ownership of the Biovail shares held by the trusts and any material increases or decreases in the percentage of such ownership, pursuant to Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2]. He did not do so.
- 193. By reason of the foregoing, Melnyk violated and, unless enjoined, will again violate Section 13(d) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13d-1 and 13d-2 thereunder [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

TENTH CLAIM FOR RELIEF Violations of Rule 302(b) of Regulation S-T

- 194. The Commission realleges and incorporates by reference herein each and every allegation contained in paragraphs 1 through 193.
- 195. Biovail did not retain and has not produced to the Commission staff upon request manually signed signature pages or other documents authenticating, acknowledging, or otherwise adopting the signatures that appear in typed form within its electronic filings on Form 20-F.
- 196. By reason of the foregoing, Biovail has violated, and unless enjoined will again violate, Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests a Final Judgment:

I.

Permanently enjoining Crombie and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 17(a) of the Securities Act [15 U.S.C. § 77q(a)].

II.

Permanently enjoining Melnyk, Crombie, Miszuk, Howling, and Biovail, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5) [17 C.F.R. § 240.10b-5], and Melnyk, Crombie, Miszuk, and Howling from aiding or abetting future violations of Sections 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5].

III.

Permanently enjoining Biovail, its agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a) and 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16] and Rule 302(b) of Regulation S-T [17 C.F.R. § 232.302(b)].

IV.

Permanently enjoining Crombie and Miszuk, their agents, servants, employees, and attorneys and all persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(b)(5) of the Exchange Act [15 U.S.C. § 78m(5)] and Rules 13b2-1 and 13b2-2 [17 C.F.R. §§ 240.13b2-1 and 240.13b2-2], and from aiding and abetting future violations of Sections 13(a) and 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(a), 78m(b)(2)(A) and 78m(b)(2)(B)] and Rules 12b-20, 13a-1, and 13a-16 [17 C.F.R. §§ 240.12b-20, 240.13a-1 and 240.13a-16].

V.

Permanently enjoining Crombie, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Rule 13a-14 of the Exchange Act [17 C.F.R. § 240.13a-14].

VI.

Permanently enjoining Melnyk, his agents, servants, employees, and attorneys and all persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, and each of them from future violations of Section 13(d) of the Exchange Act [15 U.S.C. § 78m(d)] and Rules 13d-1 and 13d-2 [17 C.F.R. §§ 240.13d-1 and 240.13d-2].

VII.

Ordering Biovail, Melnyk, Crombie, Miszuk, and Howling to disgorge any ill-gotten gains from the conduct alleged herein and to pay prejudgment interest thereon.

VIII.

Imposing civil penalties upon Biovail and Crombie pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and upon Biovail, Melnyk, Crombie, Miszuk, and Howling pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)].

IX.

Permanently barring Crombie, pursuant to Section 20(e) of the Securities Act [15 U.S.C. § 77t(e)], and Melnyk, Crombie, Miszuk, and Howling, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)], from serving as an officer or director of any issuer that has a class of securities registered under Section 12 of the Exchange Act [15 U.S.C. § 781] or that is required to file reports pursuant to Section 15(d) of the Exchange Act [15 U.S.C. § 780(d)].

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X.

Granting such other and further relief as to this Court seems just and proper.

Document 45-2

Dated: New York, New York

July 31, 2008

Andrew M. Calamari (AC-4864) Associate Regional Director Attorneys for Plaintiff SECURITIES AND EXCHANGE **COMMISSION** 3 World Financial Center New York, NY 10281-1022 (212) 336-1020

Of Counsel:

Robert J. Keyes Todd D. Brody Celeste A. Chase Catherine Smith

EXHIBIT B



CONTACT: Kenneth G. Howling Vice President, Finance (905) 286-3000

FOR IMMEDIATE RELEASE:

BIOVAIL PROVIDES GUIDANCE ON 2003 THIRD QUARTER RESULTS

TORONTO, Canada, October 3, 2003 - Biovail Corporation (NYSE, TSX: BVF) announced today that while it has not completed a final compilation and analysis of its 2003 third quarter, preliminary results indicate that revenues will be below previously issued guidance and will be in the range of \$215 million to \$235 million and earnings per share of \$0.35 to \$0.45 for the three months ended September 30, 2003. Contributing significantly to this unfavorable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a result of a traffic accident.

After leaving Biovail's Steinbach, Manitoba manufacturing facility on September 30, 2003, a truck carrying a material shipment of Wellbutrin XL was involved in a multi-vehicle traffic accident at approximately 4 p.m. eastern standard time October 1, 2003 near Chicago, Illinois. While this product may still be salable in the future, it must first be returned for inspection to Biovail's manufacturing facility in Manitoba to ensure it is still within acceptable specifications. Revenue associated with this shipment is in the range of \$10 to \$20 million. The manufacturing cost value of this shipment was fully insured.

As a result of numerous recent inquiries, Biovail also comments on two additional items associated with third quarter income.

Biovail has an economic interest in the gross profits derived from the sales of a generic version of omeprazole. The distributor of this generic omeprazole product has announced that it will provide significant price reductions on a retroactive basis to wholesalers. This distributor has also indicated that it will be lowering its financial guidance for this product given lower pricing and for competitive reasons. Biovail's second half 2003 financial guidance assumed that additional competition for generic omeprazole would seriously erode the financial benefit to the Company's interest in the gross profits of this product. However, since Biovail shares in a percentage of the gross profit of this product, significant credits issued by the distributor during the third quarter 2003 could have a negative effect on Biovail's participating interest of up to \$15 million in net income. As well, it can be anticipated that there could be a fourth quarter 2003 negative income impact of \$15 to \$20 million.

During the third quarter 2003, Biovail was working with Aventis, the supplier of branded Cardizem CD product, to alleviate a back order position that existed at the end of June 2003. Considerable progress was made in this regard during the third quarter 2003 and additional shipments from Aventis were received in Q3 however, further shipments, which had been anticipated prior to September 30, 2003, arrived immediately following quarter-end. As a result, these additional shipments will not be included in third quarter 2003 revenue as expected but will favorably impact fourth quarter 2003 revenue. During third quarter 2003, approximately half of the June 30, 2003 back order position was alleviated however, due to continued strong sales of Cardizem CD 360 mg and new orders for this dosage strength, backorders have increased to approximately \$18 million as at September 30, 2003. We will continue to work with Aventis to rectify this situation expeditiously.

Biovail management it will host a conference call and webcast on Friday, October 3rd, 2003 at 10:15 a.m. EST for company executives to discuss 2003 third quarter earnings guidance. Following the discussion, Biovail executives will address inquiries from investment analysts.

A live webcast of this call will be available through the Investor Relations section of the Biovail web site, www.biovail.com. Alternatively, please dial 1-800-884-5695 (North America.) or 1-617-786-2960 for International callers, with passcode 29341981, to access the conference call. A replay of the conference call will be available until 7:00 p.m. EST on Friday, October 10th, 2003 by dialing 1-888-286-8010 (North America) or 1-617-801-6888 for International callers, using access code, 45094403.

Biovail Corporation is an international full-service pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, sale and promotion of pharmaceutical products utilizing advanced drug delivery technologies.

For further information, please contact Ken Howling at 905-286-3000 or send inquiries to ir@biovail.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward looking and are subject to risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission.

EXHIBIT C

To:

Brian Crombie [brian.crombie@biovail.com] Thursday, October 02, 2003 3:56 PM Ken Howling



Biovall announces a profit war...

<< Biovail announces a profit warning for Q3.doc>>

Brian Crombie

SVP and CFO Biovail Corporation 905-286-3010

FOIA Confidential Treatment Requested BVF120424

Confidential Treatment Claimed Under FOIA by Fried, Frank, Harris, Shriver & Jacobson LLP KH 000126 Biovail announces a profit warning for Q3, 2003.

Early in the morning on October 1, 2003 two semi trailer trucks carrying a material shipment of Biovail product were involved in a chain reaction accident in Chicago, Illinois with another truck and a tour bus. Eight people were killed and 16 injured, most of them members of International Woman's Associates, a group of foreign women living in the Chicago area. Biovail expresses its deepest condolences to the families of the victims.

The Biovail product was a material amount of Buproprian being shipped to Biovail's licensee. This product must be returned to Biovail's manufacturing plant in Manitoba Canada to ensure it is still within specifications. Since the supply agreement between Biovail and its licensee stipulates FOB the licensee's warehouse, the revenue on this product cannot be recognized in Q3, 2003. The product, either the existing shipment once approved, or replacement shipment will be shipped within ten days. However this replacement shipment and its associated revenue will now be recognized in Q4 not Q3.

Separetely, Biovail has been working with its supplier of Cardizem CD, Aventis, to alleviate a material back order position that existed in June 2003. As of September 30th about half of the back order position has been alleviated. A sizable shipment from Aventis that was hoped for by September 30 actually arrived today and will therefore not. be included in revenue for Q3 as was hoped, but in Q4.

In addition, it has come to Biovail's attention that Schwartz Pharma, the distributor of generic omeprazole developed by Pharmapass, a company owned by Biovail, has in Q2 provided significant price reductions on a retroactive basis to its wholesalers. Since Biovail shares in a percentage of the gross profit of this product, significant credits will have the effect of creating a negative participating interest, at least for one month in the quarter. The total effect of these sizable credits and the decline in revenue due to competition is not know at this time but is expected to be material. While this negative impact will reduce total revenue in a material amount because of the corresponding reduction in amortization, it will have a material impact, but less of one, on the company's net income.

Finally, Biovail will be taking a restructuring charge in Q3 associated with its move of its US operations from Raleigh Durham North Carolina to Bridgewater New Jersey. While this amount will be excluded from EPS before certain charges it will be included in the US GAAP financial statements and thereby having a negative impact on the quarters GAAP reported net income.

While the complete impact of the above items is not known at this time the Company felt it important to release this earnings warning. While all of these financial items are regrettable none of them impact the long-term confidence the company has in its future.

FOIA Confidential Treatment Requested BVF120425

Of far greater concern than Biovail's financial results are the victims of this terrible accident. Biovail is deeply concerned about the drivers of the vehicles and the victims and will do all it can to help those impacted. The company regrets having to associate such a terrible accident with an announcement of its impact on the Company's quarterly earnings but has a public disclosure requirement to do so. Eugene Melnyk, the Company's Chairman and CEO will be attending a memorial service

FOIA Confidential Treatment Requested BVF120426

EXHIBIT D

From:

Ken Howling

Sent:

Wednesday, October 08, 2003 5:09 PM

To:

Brian Crombie

Subject:

FW: DRAFT Press Release

Eugene has edited this. The last sentence now reads that we reconfirm that the value of the good is as per our previously stated guidance. (PERIOD).

----Original Message-From: Ke

Ken Howling

Sent:

Wednesday, October 08, 2003 12:54 PM

To:

Eugene Melnyk Naomi Nemeth

Subject:

FW: DRAFT Press Release

Brian has added some comments to the last line for everyone's consideration as a big question is why don't we know the exact value. Also, the guy at GSK is not responding to multiple voice mail, emails and no assistant is available. I will now reach out to their Communications Group. Please let Naomi know if you are OK with Brian's edit and if she should go ahead and get this formatted. I have not contacted the Exchanges as I am trying to get a hold of GSK first.

----Original Message----

From:

Naomi Nemeth

Sent:

Wednesday, October 08, 2003 12:40 PM

To: Cc: Eugene Melnyk Ken Howling

Subject:

DRAFT Press Release

Ken added a statement about bulk tablets to the first line:

BIOVAIL CONFIRMS WELLBUTRIN XL SHIPMENT RECOVERY

TORONTO, Canada, October 8, 2003 - Biovail Corporation (NYSE, TSX: BVF) today confirmed that it has recovered the Wellbutrin XL shipment, which included bulk tablets, involved in a traffic accident on October 1, 2003. Although further testing is required at Biovail's Steinbach, Manitoba manufacturing facility, Biovail confirmed that approximately 60% of the shipment is salable and may be re-shipped within the next 30 days.

Furthermore, Biovail re-confirms that the sales value of these goods is within previously stated guidance of \$10 to \$20 million BASED UPON ESTIMATED GROSS SALES PRICE, GROSS TO NET DISCOUNTS AND TIERED PRICING ASSUMPTIONS.